

Protocol Title: Behavior Modification Comparison
Study: comparison between the 12-week Group
Lifestyle Balance (GLB) Program and the 6-month
Sensible Weigh program.

Nelson

FDG20110028E

DGMC Exempt Research Final Report Template

**60th Medical Group (AMC), Travis AFB CA
INSTITUTIONAL REVIEW BOARD (IRB)
Exempt Protocol Final Report**

APPROVED

APR 14 2014

(Please type all information. Use additional pages if necessary.)

Protocol: FDG20110028E

Date report Submitted: 17 March 2014

**60MDG IRB
TRAVIS AFB CA**

**Protocol Title: Behavior Modification Comparison Study: comparison between the 12-week Group
Lifestyle Balance (GLB) Program and the 6-month Sensible Weigh program.**

Principal Investigator: Mary Nelson, PhD, RN

Office Symbol: SGSE

Phone: 707 423 7263

1. **Initial Approval Date: 24 May 2011**

2. **Protocol Exemption Category**

(check all that apply)

32CFR219.101 (b) (1) ☐ (2) ☒ (3) ☐ (4) ☐ (5) ☐ (6) ☐

3. **Protocol Outcome Summary**

Were the protocol objectives met, and how will the outcome benefit the DOD/USAF?

Protocol Objectives:

The objective of the protocol was to determine if participants that completed the Sensible Weigh program would demonstrate larger weight loss due to the longer length of the program and individualized follow-up as compared to shorter Group Life Style Balance (GLB) Program. Other factors that were compared in both programs include: weight loss, activity, and nutrition knowledge improvements. Finally retention rates were compared between both intervention programs and other barriers.

Materials and methods:

This was a two-group comparison study, consisting of an anonymous survey that was completed by military beneficiaries participating in the 12-week GLB program or 6-month Sensible Weigh program at the Nutrition Clinic at DGMC. The survey assessed weight change, general nutrition knowledge, subject demographics, activity, assessment of "stages of change," and any known barriers. Participants were scheduled into one of the two behavior modification programs based

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14. ABSTRACT

Purpose: The objective of this was to determine if participants that completed the Sensible Weigh program would demonstrate larger weight loss due to the longer length of the program and individualized follow-up as compared to shorter Group Life Style Balance (GLB) Program. Other factors that were compared in both programs include: weight loss, activity, and nutrition knowledge improvements. **Methods:** This was a two-group comparison study, consisting of an anonymous survey that was completed by military beneficiaries participating in the 12-week GLB program or 6-month Sensible Weigh program at the Nutrition Clinic at DGMC. Participants were scheduled into one of the two behavior modification programs based on current clinical protocols, either referred by their primary care provider, or self-referred to the nutritional medicine clinic. Surveys were completed at the first session, and then at the final session of the course. **Results:** A total of 125 initial surveys were completed, with 66 (52.8%) final surveys returned. Twenty-two of the 50 (44%) Sensible Weigh participants and 44 of the 75 (58.7%) of the GLB participants completed a final survey. Sensible Weigh participants were more likely to be younger, but other demographic measures were similar between groups. Overall, there was no statistically significant difference between programs in self-reported weight loss, exercise, eating habits and knowledge level compared to baseline. However, there was a significant difference in the overall change to the self-reported stage of change ($p=0.012$), with participants in the Group Lifestyle Balance program more likely to stay the same or increase their change behaviors. **Discussion:** The results of this study were unable to determine a clear advantage with either lifestyle modification program, although this is likely due to the inherent limitations to the study. However, the lack of a significant difference in outcomes suggests that the differences are not likely to be clinically significant, and the selection of either program could be made in order to best fit the available resources of the Nutritional Medicine Clinic and the needs of the patient population.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:

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OF PAGES**14**19a. NAME OF
RESPONSIBLE PERSON

on current clinical protocols, either referred by their primary care provider, or self-referred to the nutritional medicine clinic.

At the first session in either the Sensible Weigh or GLB program, participants were invited to fill out an anonymous survey. The survey contained questions on one page, with a sheet of carbon paper, to transfer their responses to a second page. On the back side of the second page was a survey to be completed at the final session of the course. Using the carbon copy allowed the ability to link both pre- and post- training information, but still maintain anonymity. Subjects who did not complete of the lifestyle intervention programs were asked to submit the Final Day Survey at the time they drop out of the program. A small incentive was offered to participants that complete the survey each time.

Results: attached document ("include for report")

Conclusion/applications:

The design of the study did not allow for random assignment to different classes, and because of changes to the Nutrition Medicine Clinic schedule, only 50 of the proposed 75 participants in the Sensible Weigh program completed an initial survey. Subsequent analysis demonstrated that participants in each group were unequally distributed between programs by age group.

Overall survey completion rates were similar to what had been anticipated, but the total number of responses from those in the Sensible Weigh program (n=22) was the primary limitation to determine statistical significance the outcomes, particularly with weight loss, exercise, eating habits and knowledge level. However, there was a significant difference in the overall change to the self-reported stage of change ($p=0.012$), with participants in the Group Lifestyle Balance program more likely to stay the same or increase their stage of change.

The results of this study are unable to determine a clear advantage with either lifestyle modification program, although this is likely due to the inherent limitations to the study. However, the lack of a significant difference in outcomes suggests that the differences are not likely to be clinically significant, and the selection of either program could be made in order to best fit the available resources and skills of the Nutritional Medicine Clinic.

4. Protocol Status

Check one only

- ☐ Inactive, protocol never initiated
- ☐ Inactive, protocol initiated but has not/will not be completed
- ☒ All approved procedures/uses have been completed

5. **Number of Amendments to Study:** ONE

Date(s) of Amendment(s): 07Jun2013

6. **Funding**

Source of Funding _____ Clinical Investigation Facility _____

Funding allocated since start of study ___\$2,938___ Funds remaining ___\$0.00___

7. **Study Personnel Changes**

Have there been any Principal or Associate Investigator Personnel changes since approval, last review protocol, or annual review? ☒ Yes ☐ No

Name	Rank	Study Role	Date of Investigator Training	Staff/ Resident/ Fellow/ Civilian	Dept/ Office Symbol	Addition or Deletion	Date of Change
Mary Nelson	CIV	PI	6/30/2011	Staff	60 ADMS/ HAWC	Addition	07Jun2013
Jennifer Hatzfeld	Lt Col	AI	3/2/2011	Staff	60 MDG/ SGSE	Addition	07Jun2013

8. **Manpower**

List manpower expended on this study

Rank	AFSC	# hours duty time	# hours off-duty time
Major	46N3	25 hours	0
Contractor	Diabetes CRC	25 hours	0
Civilian		5 hours	0

9. **Publications**

Were there any publications as a result of this research? N/A

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PI Last Name: Nelson

FDG#: FDG20110028E

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N/A

10. **Signatures**


(PI / AI Signature)

Mar 17, 2014
(Date)

Abstract – Comparison Study

Purpose:

The objective of this was to determine if participants that completed the Sensible Weigh program would demonstrate larger weight loss due to the longer length of the program and individualized follow-up as compared to shorter Group Life Style Balance (GLB) Program. Other factors that were compared in both programs include: weight loss, activity, and nutrition knowledge improvements.

Methods:

This was a two-group comparison study, consisting of an anonymous survey that was completed by military beneficiaries participating in the 12-week GLB program or 6-month Sensible Weigh program at the Nutrition Clinic at DGMCC. Participants were scheduled into one of the two behavior modification programs based on current clinical protocols, either referred by their primary care provider, or self-referred to the nutritional medicine clinic. Surveys were completed at the first session, and then at the final session of the course.

Results:

A total of 125 initial surveys were completed, with 66 (52.8%) final surveys returned. Twenty-two of the 50 (44%) Sensible Weigh participants and 44 of the 75 (58.7%) of the GLB participants completed a final survey. Sensible Weigh participants were more likely to be younger, but other demographic measures were similar between groups. Overall, there was no statistically significant difference between programs in self-reported weight loss, exercise, eating habits and knowledge level compared to baseline. However, there was a significant difference in the overall change to the self-reported stage of change ($p=0.012$), with participants in the Group Lifestyle Balance program more likely to stay the same or increase their change behaviors.

Discussion:

The results of this study were unable to determine a clear advantage with either lifestyle modification program, although this is likely due to the inherent limitations to the study. However, the lack of a significant difference in outcomes suggests that the differences are not likely to be clinically significant, and the selection of either program could be made in order to best fit the available resources of the Nutritional Medicine Clinic and the needs of the patient population.

Analysis

A socio- demographic profile of the Study Population by Group was obtained. Between group differences on socio demographic characteristics were analyzed and a Pearson Chi Square was computed.

Linear regression analysis was performed to assess the effect of Program, socio demographic characteristic and Stage of Change on weight change.

Between group differences in exercise, eating and knowledge outcomes were assessed using the Mann-Whitney test.

Overall change to the self-reported Stage of Change (from Stage 1, Pre-contemplative, to Stage 5, the Maintenance Phase) were compared using Pearson Chi Square analysis.

Results

Sixty-six (52.8%) of the 125 participants enrolled in the study completed a follow-up survey, although not all respondents answered every question.

The between- group comparisons of characteristics of participants completing the initial survey are shown in Table 1.

Table 1. Socio-demographic Characteristics, by Study Group (N=125)

Age Group	Program	
	SW	GLB
1	2 (.40)	0 (0.00)
2	12 (66.67)	6 (33.33)
3	14 (51.85)	13 (48.15)
4	17 (34.69)	32 (65.31)
5	5 (17.24)	24 (82.76)

Pearson Chi2(4) 16.74

Pr=0.002

Gender	Program	
	SW	GLB
Male	12 (.24)	38 (.76)
Female	25	50

(.33) (.66)

Pearson Chi2 (1) 1.254 Pr 0.263

Program		
Rank	SW	GLB
1	5 (.71)	2 (.28)
		59
2	35 (.37)	(.63)
		59
3	3 (.60)	(.40)
		12
4	6 (.33)	(.66)

Pearson Chi2 (3)
.35 Pr .22

Program		
Race		
1	10 (.33)	20 (.66)
2	5 (.24)	16 (.76)
3	27 (.46)	32 (.54)
4	4 (.44)	5 (.54)
6	1 (.50)	1 (.50)
9	3 (.75)	1 (.25)

Pearson chi2(5) = 5.8647 Pr = 0.320

The results of the linear regression analysis are given in here, based on the data provided by the 58 participants completing the final survey.

Model 1: Weight Loss Given Program-A lone (n=58)

Variable	T score; Pr	CI	Coefficient (se)	R2	F; Pr
				0.05	3.44; 0.069
Program	1.85; 0.069	-0.37- 9.59	4.612821 (2.48)		

Model 2: Weight Loss Given Program and Age Group

Variable	T score; Pr	CI	Coefficient (se)	R2	F; Pr
				0.1255	.3.95; .025
Program	.77; 0.445	-3.34 - 7.51	2.087542 (1.19)		
Age Group	2.06; .004	.0697755	4.86751	0.1255	

Model 3: The Effect of Program and Gender on Weight Change

Variable	T score; Pr	CI	Coefficient (se)	R2	F; Pr
				0.1547	5.03; 0.009
Program	2.09; 0.041	.2114- 9.759	4.985688 (2.38)		
Gender	-2.51	- 11.29273 — 1.266108	-6.27942 (2.50)		

Model 4: The Effect of Program and Race on Weight Change

Variable	T score; Pr	CI	Coefficient (se)	R2	F; Pr
				0.0605	1.77; 0.179
Program	1.76; 0.084	-.617- 9.543	4.462991 (2.53)		
Race	-0.40; 0.694	-2.592- 1.738	-.4270153 (.08)		

Model 5: The Effect of Program and Rank on Weight Change

Variable	T score; Pr	CI	Coefficient (se)	R2	F; Pr
				0.053	1.52; .2277
Program	1.74; 0.088	-. .6897643- 9.652432	4.481334 (2.57)		
Rank	0.24; .905	-. 2.717333- 3.447025	.3648462 (1.53)		

Variable	T score; Pr	CI	Coefficient (se)	R2	F; Pr
				0.191	2.41; .049
Program	0.79; 0.432	-3.617- 8.327	2.35495 4 (2.97)		
Age Group	1.55; 0.126	-.597- 4.702	2.05256 7 (1.32)		
Gender	-1.86; 0.069	-10.381-.4049	- 4.98882 1(1.55)		
Rank	-0.06; 0.950	-3.180-2.987	- .096723 9 (1.53)		

Model 7: Effect of Program and Stage of Change on Weight Change

Variable	T score; Pr	CI	Coefficient (se)	R2	F; Pr
				0.065	1.92; 0.15
Program	1.91; 0.61	-.238-9.85	4.080 (2.51)		
Stage of Change	0.66; .0513		.792 (1.20)		

Model 8: Effect of Program Age Group Gender Race Rank Stage of Change on Weight Change

Variable	T score; Pr	CI	Coefficient (se)	R2 0.217	F2 2.32; Pr .057
Program	0.77; 0.447	-3.67-8.19	2.26832 (2.95)		
Age Group	1.82 (0.76)	-.2599-5.137	2.438903 (1.34)		
Gender	-1.91; .0.062	-10.45-.267	-5.0930 (2.68)		
Race	-0.74;0.461	-2.973-1.368	-.8027021		
Rank	-0.39; 0.695	-3.789-2.546	-.8027 (1.08)		
Stage of Change	0.66; 0.785	-1.61-3.19	.790 (8 (1.20)		

Table 2. Behavior Change, by Group

Exercise

Group	obs	rank sum	expected
-----+-----			
1	23	663	782
2	44	1615	1496
-----+-----			
combined	67	2278	2278

$z = -1.584$

Prob > |z| = 0.1131

Eating Habits

$z = -1.584$

Prob > |z| = 0.1131

Knowledge

Group	obs	rank sum	expected
-----+-----			
1	22	685.5	737
2	44	1525.5	1474
-----+-----			
combined	66	2211	2211

$z = -0.706$

Prob > |z| = 0.4800

Table 3. Effect of program on change to self-reported 'Stage of Change' (n=63)

Change to Stage of Change	Sensible Weigh	Group Lifestyle Balance	Total
-2 (Stage of change lowered by two categories)	3	0	3
-1 (Stage of change lowered by one category)	5	1	6
0 (Stage of change remained the same)	4	12	16
1 (Stage of change increased by one category)	7	17	24
2 (Stage of change increased by two categories)	3	8	11
3 (Stage of change increased by three categories)	0	3	3
Total	22	41	63

Pearson Chi2(5) == 14.7142 Pr = 0.012

Discussion

The design of the study did not allow for random assignment to different classes, and because of changes to the Nutrition Medicine Clinic schedule, only 50 of the proposed 75 participants in the Sensible Weigh program completed an initial survey. Subsequent analysis demonstrated that participants in each group were unequally distributed between programs by age group.

Overall survey completion rates were similar to what had been anticipated, but the total number of responses from those in the Sensible Weigh program (n=22) was the primary limitation to determine statistical significance the outcomes, particularly with weight loss, exercise, eating habits and knowledge level. However, there was a significant difference in the overall change to the self-reported stage of change ($p=0.012$), with participants in the Group Lifestyle Balance program more likely to stay the same or increase their stage of change.

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